

NOV - 9 2000

Page 1 of 2

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K002805

1. Submitter's Identification:

Kendro Laboratory Products, L.P.
31 Pecks Lane
Newtown, CT 06470

Contact: Gail Y. Daunis
Quality & Regulatory Specialist

Date Summary Prepared:

August, 2000

2. Name of the Device:

Kendro Heracell CO₂ Incubator

3. Predicate Device Information:

ThermoQuest Corp. (Forma Scientific, Inc), Mill Creek Road, Marietta, GA , K#991408,
"ThermoQuest Universal Water-Jacketed Incubators - Forma Scientific Incubator".

4. Device Description:

The Kendro Heracell CO₂ Incubators are bench top or floor standing units. They control CO₂ (T/C), temperature (by independent digital controller with a separate switching device), provide elevated humidity, and feature a decontamination mode (Contra Con) automatic decontamination routine) incorporating humid heat at 90°C. Consistent culture conditions throughout the interior are achieved by the air jacket temperature control and exact simulation of physiological conditions. Controlled parameters and alarm functions are microprocessor controlled. The volume of the chamber is 151 liters.

5. **Intended Use:**

The intended use of this incubator is to provide an environment with controlled temperature, CO₂ elevated humidity, and an automatic decontamination mode, for the development of ova or embryos at or near body temperature.

6. **Comparison to Predicate Devices:**

The two (2) devices are very similar except that the Kendro device does not control oxygen at suppressed levels and the Forma device does not feature the temperature incubation and Contra Con automatic decontamination mode. The Kendro device temperature incubations mode range is +3°C above ambient to 55°C whereas the Forma device temperature range is +5°C above ambient to 55°C. The Forma temperature safety controller is independent analog electronics, whereas the Kendro devices' temperature safety controller is an independent digital controller with a separate switching device.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The Kendro Heracell CO₂ Incubator underwent and passed electrical safety electromagnetic compatibility, environmental and operating performance testing.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The Kendro Heracell CO₂ Incubator has the same intended use and similar technological characteristics as the predicate device, ThermoQuest (Forma Scientific Incubator) Universal Water Jacketed Incubator. Moreover, bench testing, validation testing, electrical, mechanical and environmental testing demonstrate that any differences in the technological characteristics do not raise any new questions of safety and effectiveness. Thus, the Kendro Heracell CO₂ Incubator is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 9 2000

Kendro Laboratory Products
c/o Ms. Susan Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd.
GREAT NECK NY 11021

Re: K002805
Kendro Heracell CO₂ Incubator
Dated: September 6, 2000
Received: September 8, 2000
Regulatory Class: II
21 CFR §884.6120/Procode: 85 MQG

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Page 1 of 1

510(k) Number (if known): K002805

Device Name **Kendro Heracell CO₂ Incubator**

Indications For Use:

The intended use of this incubator is to provide an environment with controlled temperature, CO₂ elevated humidity, and an automatic decontamination mode, for the development of ova or embryos at or near body temperature.

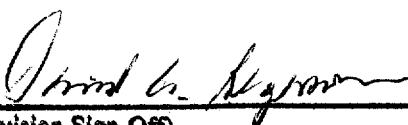
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002805